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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,427	12/19/2001	Nahid S. Waleh	8500-0270	3700

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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	13

DATE MAILED: 10/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,427	WALEH ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *4-9,12,14,16-35 and 44-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10,11,14,15 and 36-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 12.19.01 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 8 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 9 and species election with traverse of narcolepsy is acknowledged. The traversal is on the ground(s) that the species selection is overly narrow and that insomnia, narcolepsy, jet lag, and age-related sleep disorders are subspecies of the species "sleep disorders". This is not found persuasive because sleep disorders do not have common or related causes, have different clinical features, and are treated with different agents, and require different searches. For example, insomnia is treated with such drugs as benzodiazepine hypnotics, while narcolepsy is treated with stimulants (Vgontzas et al., Ann. Rev. Med. 1999, vol. 50, pp. 387-400). Thus they are not linked by cause, treatment, or clinical characteristics.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-61 are pending in this application. Claims 1-3, 10, 11, ~~14~~ 17, 15, and 36-43 are under examination; claims 4-9, 12, ~~14~~ 13, 16-35, and 44-61 are withdrawn from consideration as being drawn to a non-elected invention or species. Applicant's remarks with respect to the consideration of other species, should a generic claim be found allowable, are acknowledged.

Specification

2. The use of several trademarks has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 19, 11, 14, 15, and 36-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman,* (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims, as they pertain to the elected species, are drawn to methods of treating narcolepsy by increasing hypocretin production. What the specification teaches, however, is that interferons decrease hypocretin production. No agents that increase production are exemplified. No characteristics of such agents are described and no means by which one of skill in the art could identify them are provided. Applicant's disclosure of a single class of inhibitor provides no guidance as to how the skilled artisan could make and use activators, as would be required to affect narcolepsy. The art fails to provide compensatory teachings. Lammers et al. (Expert Opin. Pharmacother. 2003, vol. 4, pp. 1739-1746) teaches that "both patients and physicians

eagerly await for hypocretin agonists to become available". Furthermore, Lammers et al. teaches, and Applicant states on p. 6, that narcolepsy appears to be due to destruction of hypocretin-secreting neurons. Thus molecules that increase secretion would not predictably affect narcolepsy, if the cells capable of producing hypocretin are lost. Thus, since no activators are disclosed, and no means by which one of skill might make or predictably identify such activators are disclosed, and the art teaches that no means of increasing hypocretin levels are available, and further since such a treatment would not predictably affect narcolepsy, it would require undue experimentation for one of skill in the art to practice the claimed invention. In addition, the link between hypocretin and narcolepsy does not render it predictable, absent further evidence, that increasing hypocretin levels would improve narcolepsy. Biological systems are complex and the effects of changing one parameter may not be sufficient for the desired result. For example, Applicant has shown that interferons decrease hypocretin, and thus, by a simple model, would be predicted to cause sleepiness. However, a common side effect of interferon treatment is in fact insomnia. Thus, even were agents capable of increasing hypocretin production known in the art, their effects on narcolepsy would still be unpredictable and it would require undue experimentation for the artisan to use them with success.

5. Claims 1-3, 19, 11, 14, 15, and 36-43 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to methods of treating narcolepsy by increasing hypocretin production. Applicant has identified no molecules capable of such an increase and has described no characteristics of such molecules. As stated above, the art further fails to provide such molecules. Thus, one of skill in the art would not conclude that Applicant was in possession of hypocretin activators or of methods of using them.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 27, 2003

JANET ANDRES
PATENT EXAMINER